DEPARTMENT OF HEALTH & HUMAN SERVICES M928N

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2938532

May 21, 1997

Jerry M. Jones
Chief Executive Officer
Apria Healthcare, Inc.
3560 Hyland Avenue
Costa Mesa, California 92626

WARNING LETTER

Dear Mr. Jones:

An inspection of your medical gas manufacturing facility located at 4244 South Market Court, Suite A, Sacramento, California, was conducted on April 10 and 15, 1997, by Food and Drug Administration (FDA) Investigator Karen G. Hirshfield. The inspection revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act) as follows:

VIOLATION	BRIEF DESCRIPTION
501(a)(2)(B)	Your drug product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with the current Good Manufacturing Practice (GMP) regulations (Title 21, Code of Federal Regulations, parts 210 and 211), for the following specific reasons:

1. you have failed to assay the incoming liquid Oxygen U.S.P. for identity and strength prior to filling the liquid home units [21 CFR 211.165(a)]. You did not have the documentation, in the form of bulk receipt/delivery vessel Fill logs, to show that seven of the last twenty-eight oxygen deliveries were assayed for identity and

strength. A records review by our investigator covered the period of January 3 to April 8, 1997 and revealed seven dates for which no fill logs were completed. The dates for which there are no fill logs are: January 24 and 28, 1997; February 4, 7, and 11, 1997; and March 11 and 25, 1997. The missing fill logs were not discovered by your firm until after our investigator brought them to the attention of your site manager. Also, a quality assurance review of the fill logs, as required by your firm's procedures, was not being conducted.

2. you failed to properly calibrate the oxygen analyzer used for the assay of oxygen, U.S.P., in that a performance of the battery check or the weekly filter check was not conducted according to the manufacturer's instructions [21 CFR 211.160(b)(4)].

3. you failed to follow written procedures with respect to the testing of incoming liquid oxygen, U.S.P.; the calibration of the oxygen analyzer; the labeling of cryogenic home vessels; and a reviewer's signature on the manufacturing logs [21 CFR 211.100(b)].

503(b)(4) The drug product, Oxygen U.S.P., is misbranded in that it is regarded as a prescription drug and the labeling on the cryogenic home vessels fails to bear the statement, "Caution: Federal law prohibits the dispensing without a prescription" [21 CFR 201.100(b)(1)].

The above enumeration of deficiencies should not be construed as a complete list of deficiencies at your Sacramento facility. It is your responsibility to insure that all of your facilities are in complete compliance with all aspects of the Act.

The Act prohibits the introduction or delivery for introduction into interstate commerce of any adulterated and/or misbranded drug [Section 301(a)]. The Act also prohibits the adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of labeling of, or the doing of any other act with respect to a drug, if such act is done which such drug is held for sale (whether or not the first sale) after shipment in interstate commerce and results in the drug being adulterated or misbranded [Section 301(k)]. Adulterated and misbranded drugs may be seized under authority of the Act (Section 304).

A copy of the Form FDA-483 (Inspectional Observations), which was presented to Center Manager, Judy C. Cook, is enclosed for your reference. I have also enclosed a copy of the FDA's booklet entitled Compressed Medical Gases Guideline, a copy of a speech by Mr.

Duane Sylvia of FDA's Office of Compliance, Division of Manufacturing and Product Quality, Center for Drug Evaluation and Research, and 21 CFR part 210 and 211. The Compressed Medical Gases Guideline and Mr. Sylvia's speech contain useful information on how to comply with the requirements of 21 CFR part 210 and 211.

We acknowledge your response, dated April 24, 1997, concerning our investigator's observations noted on the form FDA 483. A follow-up inspection will be scheduled to ascertain adequate compliance with regulations.

Please address future correspondence to the Drug Team Leader, Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Charles D. Moss

for Patricia C. Ziobro
District Director
San Francisco District

cc: Michael J. Thiele, Branch Manager
4244 South Market Court, Suite A
Sacramento, California 95834

Enclosures:
FDA 483
21 CFR parts 210 and 211
Speech by Mr. Duane Sylvia
Compressed Medical Gases Guideline